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Report of the Certificate of Need Task Force

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Chairman, MHCC

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Chairman, CON Task Force

Introduction

Purpose of the CON Task Force

The goal of the CON Task Force is to enhance the credibility and integrity of the Certificate of Need program in a dynamic and evolving health care system, by conducting a stakeholder driven review, using a combination of a broadly representative Task Force and public comment process, to gain insight and make recommendations to enhance and improve the program. The objectives of the CON Task Force are to:

- Review and recommend modifications in the scope of services and facilities regulated under the Certificate of Need program.
- Review and recommend enhancements in the Certificate of Need application review process.
- Review and recommend enhancements in the monitoring of Certificate of Need projects under development.

CON Task Force Composition

The CON Task Force was established by Stephen J. Salamon, Chairman of the Maryland Health Care Commission. The 24-member CON Task Force is chaired by Commissioner Robert E. Nicolay. Commissioners Robert E. Moffit, Ph.D. and Larry Ginsburg also serve on the Task Force. Members of the Task Force include representatives of the Maryland Hospital Association, Med-Chi, CareFirst BlueCross BlueShield, Health Facilities Association of Maryland, LifeSpan, Hospice Network of Maryland, Maryland Ambulatory Surgical Association, and other interested organizations (Appendix A provides a list of CON Task Force members).

I. Recommendations of the CON Task Force

Principles to Guide the CON Program

Maryland's Certificate of Need program should:

- respond to its residents' needs for health care services, including hospital, long term care, ambulatory surgery, and specialized services,
- promote the quality and safety of these services,
- promote improved access to these services by underserved populations, and
- promote the affordability of health care available to Maryland residents.

Certificate of Need should be applied only in situations where unrestricted competition through normal market forces is likely to result in:

- significantly higher or unnecessary costs to the system,
- decreased access to care by vulnerable populations or less populous regions of the state, or
- a diminution of the quality or safety of patient care.

The Certificate of Need program should be:

- procedurally clear, consistent, and timely;
- flexible enough to accommodate unique situations, whether of provider mission, geography and demographics, or technological advances; and
- specific to Maryland's unique policy and regulatory framework.

The State Health Plan standards, review criteria, and associated data used to conduct Certificate of Need reviews should be kept current, and regularly updated.

Traditionally, the CON process in Maryland has been a natural component of state health planning, a process for assuring access to high quality health care services and controlling health care costs. This planning approach is based on the observation that competition and market forces do not always produce the most appropriate allocation of health care resources or the best outcomes. The CON process encompasses a fundamental review of need and resource allocation, but also brings standards to bear at the time of review that are intended to improve the quality of care and patient safety.

CON is applied to a range of different situations with somewhat different rationales:

- **Major capital investments**. Where large capital investments are involved, market forces may not appropriately match investments to community and regional needs. Because any given area has only one or a limited number of hospitals and because barriers to new competitors are high, the market for hospital services is unusual. Rather than leading to innovation and lower costs, unregulated competition may be wasteful This use of CON addresses escalating health care costs by limiting investment when need cannot be

shown. This use of CON also addresses access to quality services by regulating the location of new facilities.

- **Services with a volume/outcome association**. When there is a well-established link between volume of specialized services and outcomes CON can be used to assure access to high quality services by attaching service volume requirements to a certificate. This process also involves an assessment of need. In the long term, surrogate quality measures like volume should be replaced by specific measures of quality and outcomes, and the up-front regulation through CON should be replaced by a meaningful, on-going licensure process that considers quantitative measures of quality and outcomes.

- **Other services**. In the case of other services, the capital investment is smaller and there is less evidence of a volume/outcome association. In some cases, such as ambulatory surgery facilities, there are specific design issues that affect safety that may warrant review. But ultimately for many of these other services, competition coupled with a rigorous recurrent licensure process may be a better strategy to assure high quality and good outcomes.

Because CON involves a careful assessment of need, it is also well suited to promote improved access to underserved populations.

The strengths of the CON process in addressing cost, quality, and access are substantial, but are accompanied by negative effects on competition. CON is inherently anti-competitive, limiting new entrants, limiting new investments, limiting the introduction of some services in response to emerging needs or consumer demand, and protecting current providers. Indeed, the CON statute appropriately requires an assessment of the impact of a proposed certificate on other providers and grants those providers special status in the review process. However, the ultimate measure of effective CON must be the impact on the interests of the citizens of Maryland, not its impact on current providers. CON should only protect current providers from potential competitors when there are strong and convincing public interest arguments.

Scope of CON Coverage

The Task Force recommends that the requirement for CON be eliminated for the following:

- Closure of health care facilities
- Clinical information technology
- Home health agencies

The Task Force discussed elimination or modification of the scope of CON coverage of hospice, obstetric, open heart surgery, organ transplant, and neonatal intensive care unit (NICU) services. No change in the scope of regulation for these services is recommended.

CON Review Process

The Task Force recommends the following:

- Increase the statutory capital expenditure review threshold from $1.25 to $10.0 million (maintain the annual adjustment for inflation)
- Modify the completeness review and project review process by requiring two conferences as a standard feature of the review of any CON application: (1) An Application Review Conference ("ARC") between staff and the applicant, which can be face-to-face or by phone conference, scheduled within the approximate time frame at which the staff currently issue completeness questions; and, (2) A Project Status Conference ("PSC") between any appointed Reviewer, the staff, the applicant, and any interested parties, in person or by phone.
- Modify the project review process by allowing for changes in a project, addressed in the PSC, that bring it in closer conformance with the State Health Plan, based on staff or the Reviewer's analysis, without penalizing such changes by adding more process or time to the review.

The Task Force reviewed the regulations governing designation of interested parties in CON reviews and recommended no changes.

State Health Plan

Because of its importance in guiding the CON review process, the Task Force recommends that the Commission undertake a comprehensive revision of the State Health Plan. In updating the State Health Plan, priority should be given to revision of the Acute Inpatient Services and Ambulatory Surgical Services chapters:

- **Acute Inpatient Services (COMAR 10.24.10)**

  The revision of the Acute Inpatient Services chapter of the State Health Plan should eliminate obsolete and redundant standards, including: .06A(2) Utilization Review Control Programs; .06A(3) Travel Time; .06A(4) Information Regarding Charges; .06A(5) Charity Care Policy; .06A(6) Compliance with Quality Standards; .06A(7) Transfer and Referral Agreements; .06A(8) Outpatient Services; .06A(9) Interpreters; .06A(10) In-Service Education; .06A(11) Overnight Accommodations; .06A(12)Required Social Services; .06A(19) Minimum Size for Pediatric Unit; .06A(20) Admission to Non-Pediatric Beds; .06A(21) Required Services When Providing Critical Care; .06A(22)Average Length of Stay for Critical Care Units; .06A(23) Waiver of Standards for Proposals Responding to the Needs of AIDS Patients; .06B(1) Compliance with System Standards; .06B(2) Duplication of Services and Adverse Impact; .06B(4) Burden of Proof Regarding Need; .06B(5)Discussion with Other Providers; .06B(9) Maximum Square Footage; .06C(2) Compliance with System Standards; .06C(3) Conditions for Approval; and, .06C(5) Maximum Square Footage-Renovations.

- **Ambulatory Surgical Services (COMAR 10.24.11)**

  The revision of the Ambulatory Surgical Services chapter should consider the implications of defining the exemption from CON regulation for establishment of single operating room ambulatory surgical facilities as an exemption for a single room for the provision of invasive procedures within a practitioners office, whether the room is a sterile operating room or a non-sterile "procedure room." This will require consideration of definitions of the terms "operating room" and "procedure room" and revised and expanded definitions of "full" and "optimal capacity" for different categories of surgical room.

The update and revision of the State Health Plan should involve technical advisory groups to obtain expertise on factors influencing the availability, access, cost, and quality of services. Other State Health Plan recommendations made by the Task Force include:

- The Commission should use the 71.4% occupancy rate assumption implied by the Office of Health Care Quality's statutory 140% licensing rule as the occupancy rate standard in acute care bed need projections for all services.

- The Commission should eliminate the prohibition against shell space for acute care hospital capital projects.

Appendix A

Maryland Health Care Commission
Certificate of Need Task Force[1]

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Commissioner Robert E. Nicolay, CPA
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Members

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[1] Terri Twilley, M.S., R.N. served as a member of the Task Force from May to July 2005.

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Appointments as of 8/11/05